

# EUA: CDC's Roles and Responsibilities

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## EUA: CDC's Roles & Responsibilities

- Supports the critical task of ensuring availability, distribution, and utilization of medical countermeasures (MCMs)
- Engages FDA and other federal/state partners to develop and establish mechanisms to facilitate widespread availability and timely access of MCMs
  - ▶ Regulatory Strategy
  - ▶ Operations and Logistics



## EUA: CDC's Roles & Responsibilities

- Submits pre-EUA and EUA requests to FDA
  - ▶ preEUA/EUA is product-specific for a threat agent
  - ▶ Includes available data to support MCM use
  - ▶ Dynamic process
  - ▶ Provisional agreements on EUA conditions
  - ▶ Communication Planning/Strategy
  
- Experiences to Date:
  - ▶ 14 preEUA and 6 EUA requests
  - ▶ 2009 President's Inauguration
  - ▶ 2009 H1N1 Public Health Emergency



## Next Steps

- Sharing of lessons learned from all stakeholders to enhance preparedness regarding stockpiling, distribution, dispensing, and utilization of MCM
- Engage in transparent and continuing dialogues among all stakeholders

